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on 12 January 2010.

PATENT
Docket No.: 019904-003010US

TOWNSEND and TOWNSEND and CREW LLP

By: Patricia Andrews

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Robin D. CLARK *et al.*

Application No.: 10/596,998

Filed: March 8, 2007

For: AZADECALIN GLUCOCORTICOID
RECEPTOR MODULATORS

Customer No.: 20350

Confirmation No.: 4531

Examiner: Zinna Davis

Art Unit: 1625

**REQUEST FOR
RECONSIDERATION OF PATENT
TERM ADJUSTMENT
DETERMINATION
UNDER 37 C.F.R. § 1.705(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Pursuant to 37 C.F.R. § 1.705(b), Applicants respectfully request reconsideration of the patent term adjustment determination. This request is accompanied by the fee set forth in § 1.18(e) and a statement of facts as required under 37 C.F.R. § 1.705(b)(2).

In view of the following it is respectfully requested that Applicants be granted a corrected patent term adjustment at least 358 days with additional term of one day for each day from today (January 12, 2010) to be added until the patent issues.

Statement of Facts as required under 37 C.F.R. § 1.705(b)(2)

The correct patent term adjustment is at least 358 days, not 0 days as stated on the Determination of Patent Term Extension under 35 U.S.C. § 154(b) mailed October 19, 2009 (*see Exhibit A*).

The period of adjustment under § 1.702(a) is 196 days (“A delay”).

The period of adjustment under § 1.702(b) is at least 187 days (“B delay”).

The period of adjustment under § 1.704(a) is 25 days (“applicant delay”).

The period of adjustment under § 1.703(f) is at least 358 days.

The Relevant Dates as Specified in 37 C.F.R. §§ 1.703(a)-(e), § 1.704 and the Adjustment Specified in 37 C.F.R. § 1.703(f)

1. § 1.703(a) as applied to U.S. National Stage Applications under § 371

Applicants **do** dispute that the Office’s calculation of 0 days of term adjustments to include the term adjustments that Applicants are entitled to under 37 CFR § 1.703(a). The instant application is a U.S. National Stage Application under § 371, with a §371(c) filing date of March 8, 2007. The Office mailed a Determination of Patent Term Extension on October 19, 2009, which accompanied the Notice of Allowance. Applicants submit that this application is ineligible for Patent Term Extension (PTE) under 37 CFR § 1.701 since this application was filed after May 29, 2000. Therefore, this application is eligible for Patent Term Adjustment (PTA) as defined under 37 CFR § 1.702.

The instant U.S. National Stage Application under § 371 was accorded a §371(c) filing date of March 8, 2007 and a first action on the merits was mailed from the Office on November 20, 2008. Applicants are entitled to 196 days of term adjustment under 37 CFR § 1.702(a)(1), the period of delay between May 8, 2008 (14 months after fulfillment of the §371 requirements) and November 20, 2008 (*see Exhibit B, Patent Term Extension History*).

2. § 1.703(b) as applied to U.S. National Stage Applications under § 371

The Office failed to issue a patent within three years of the actual filing date of the above-referenced application. Thus, Applicants **do** dispute the Office’s calculation of 0 days of term adjustments that Applicants are entitled to under 37 CFR § 1.703(b) and under § 1.702(b)

(see **Exhibit B**). Further, Applicants submit that the Office erred in its calculation of the three-year pendency provision under 35 U.S.C. § 154(b)(1)(B) since the Office failed to take into account that the date that determines the three-year provision was the commencement date as defined by 35 U.S.C. § 371(b) and (f). As stated above, the Office erroneously used the parameters of Patent Term Extension for the purposes of calculating delay and term adjustments (see **Exhibits A and B**) for the instant application.

The present application is the U.S. National Stage entry under 35 U.S.C. § 371 of International Application No. PCT/US2005/000607, filed January 10, 2005, which claims the benefit of priority of U.S. Provisional Application No. 60/535,460, filed January 9, 2004 (see face page of U.S. Patent Publication No. 2007/00203179 A1 (**Exhibit C**)). Applicants submit that the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B Delay" under 35 U.S.C. § 154(b)(1)(B), 37 C.F.R. § 1.702(b) and § 1.703(b), is the date that is 30 months from the priority date of the international application. Therefore, pursuant to the provisions of 35 U.S.C. § 371(b) and (f), the national stage for the present application "commenced" on July 9, 2006, i.e., upon expiration of 30 months from the priority date of the international application and no express request for entry was made under § 371(f).

Therefore, the period beginning on July 10, 2009 (the day after the date that is three years after July 9, 2006, the date that the national stage commenced), and ending upon issuance of a U.S. Patent for this application is the term adjustment to be accorded to the U.S. Patent. As of today's date, January 12, 2010, the term adjustment as applied under 37 C.F.R. § 1.702(b) is at least 187 days in length. This number will increase by one day for each day after January 12, 2010 (date of issue fee payment) until the U.S. Patent is issued.

3. § 1.703(c)-(e)

There are no relevant dates as specified under §§ 1.703(c)-(e).

4. **Overlapping periods under § 1.703(a)-(e)**

Applicants have calculated overlapping periods in accordance with *Wyeth v. Dudas* (88 U.S.P.Q.2d 1538, D.D.C. 2008) and affirmed by the Federal Circuit on January 7, 2010 (*Wyeth v. Kappos*, Docket No. 2009-1120, Fed. Cir.). Periods of delay under 35 U.S.C.

§154(b)(1)(A) and 35 U.S.C. §1.54(b)(1)(B) overlap only if they occur on the same calendar day or days (see *Wyeth v. Dudas* and *Wyeth v. Kappos*). Applicants submit that there are 0 days of overlap under § 1.703(a)-(e). Absent the Office taking over four months to issue the U.S. Patent, there will be 0 days of overlap for the instant application.

5. Reduction of Period of Adjustment of Patent Term Under 37 C.F.R. §1.704

Applicants **do** dispute that the Office's calculation of 0 days of term adjustments as indicated on the attached Patent Term Extension History (see **Exhibit B**). Applicants submit that the period of adjustment under § 1.704(a) is a total of 25 days. A non-final rejection was mailed from the Office on March 13, 2009, and Applicants filed the response on July 8, 2009. The period of adjustment under § 1.704(b) falls between June 13, 2009 and July 8, 2009, and the term adjustment is 25 days as shown in **Exhibit B**.

6. § 1.703(f)

The period of adjustment under 37 C.F.R. § 1.702(f) is as follows:

Type "A" delay:	196 days
Type "B" delay:	187+ days (at least 187 days)
"A" and "B" overlap:	0 days
Applicant delay	25 days
<u>Adjusted</u>	<u>358+ days</u> (at least 358 days)

Terminal disclaimer

The instant application is not subject to a terminal disclaimer.

PATENT TERM ADJUSTMENT DETERMINATION

Pursuant to *Wyeth v. Kappos* and *Wyeth v. Dudas* (Fed. Cir., Docket No. 2009-1120, January 7, 2010, and 88 U.S.P.Q.2d 1538, D.D.C. 2008) and the provisions regarding § 371 applications, Applicants are entitled to at least 358 days of patent term adjustment, *i.e.*:

[383+ days (A delay + B delay) minus 0 overlap days] minus [25 days (applicant delay)].

Based on the foregoing, Applicants respectfully request reconsideration of the patent term adjustment determination. Applicants further request that the decision regarding "B" Delay be held in abeyance until the U.S. Patent issues for the instant application since the Federal Circuit has affirmed the interpretation of calculating delay under the provisions of 35 U.S.C. § 154(b) (see *Wyeth v. Kappos*, Docket No. 2009-1120 (Fed. Cir. Jan. 7, 2009)).

Please charge the fee set forth in 37 C.F.R. §1.18(e) (\$200.00) to Deposit Order Account No. 20-1430. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 20-1430.

Respectfully submitted,

/Alexander R. Trimble/

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**EXHIBIT A****UNITED STATES PATENT AND TRADEMARK OFFICE**

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,998	03/08/2007	Robin D. Clark	019904-003010US	4531
20350	7590	10/19/2009	EXAMINER	
DAVIS, ZINNA NORTHINGTON				
ART UNIT			PAPER NUMBER	
1625			DATE MAILED: 10/19/2009	

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Determination of Patent Term Extension under 35 U.S.C. 154 (b)
(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

EXHIBIT B

10/596,998 AZADECALIN GLUCOCORTICOID RECEPTOR MODULATORS

01-08-
2010::14:58:18**Patent Term Extensions**

Patent Term Extension (PTE) for Application Number: 10/596,998

Explanation Of Calculations

Filing or 371(c) Date:	03-08-2007	USPTO Delay (PTO) Delay (days):	0
USPTO Adjustment (days):	+0	Corrections (APPL) Delay (days):	0
		Total PTE (days):	0

Patent Term Extension History

Date	Contents Description	PTO(Days)	APPL(Days)
10-19-2009	Mail Notice of Allowance		
10-16-2009	Document Verification		
10-16-2009	Notice of Allowance Data Verification Completed		
10-06-2009	Examiner's Amendment Communication		
10-05-2009	Examiner Interview Summary Record (PTOL - 413)		
07-30-2009	Date Forwarded to Examiner		
07-08-2009	Response after Non-Final Action	Applicant Delay: 25 days (btwn 6/13/09 and 7/8/09)	
07-08-2009	Request for Extension of Time - Granted		
03-13-2009	Mail Non-Final Rejection		
03-12-2009	Non-Final Rejection		
03-08-2007	Information Disclosure Statement considered		
01-12-2009	Date Forwarded to Examiner		
12-15-2008	Response to Election / Restriction Filed		
11-20-2008	Mail Restriction Requirement	← 1st action on merits	
11-20-2008	Requirement for Restriction / Election		
05-02-2008	Preliminary Amendment		
10-17-2007	Filing Receipt - Corrected		
08-30-2007	PG-Pub Issue Notification		
07-21-2007	Case Docketed to Examiner in GAU		
06-26-2007	IFW TSS Processing by Tech Center Complete		
03-08-2007	Reference capture on IDS		
03-08-2007	Information Disclosure Statement (IDS) Filed		
06-19-2007	Application Dispatched from OIPE		
03-08-2007	371 Completion Date	← 371(c) date	
05-24-2007	Sent to Classification Contractor		
05-24-2007	Notice of DO/EO Acceptance Mailed		
03-08-2007	Information Disclosure Statement (IDS) Filed		
03-08-2007	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant	NOTE: 371(b) expiration: 07-09-2006	

Close Window

"A" Delay: 5/8/2008 thru 11/20/2008 = 196 days

"B" Delay: 7/10/2009 thru today's date (1/12/2010) = 186 days

7/10/2009 thru issuance of patent = not yet determined

(19) **United States**(12) **Patent Application Publication** (10) **Pub. No.: US 2007/0203179 A1**
(43) **Pub. Date: Aug. 30, 2007**(54) **AZADECALIN GLUCOCORTICOID
RECEPTOR MODULATORS**

(86) PCT No.: PCT/US05/00607

§ 371(c)(1),

(2), (4) Date: Mar. 8, 2007

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Harlow (ES); **David Clark**, Harlow
(GB); **Karen Williams**, Harlow (ES)**Related U.S. Application Data**(60) Provisional application No. 60/533,460, filed on Jan.
9, 2004.**Publication Classification****Correspondence Address:****TOWNSEND AND TOWNSEND AND CREW,
LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834 (US)**(51) **Int. Cl.****A61K 31/47** (2006.01)**C07D 217/04** (2006.01)**C07D 217/08** (2006.01)(52) **U.S. Cl.** **514/309; 435/7.23; 546/139;
546/140; 546/141; 546/146;
546/151**(73) Assignee: **Concept Therapeutics, Inc.**, Menlo Park,
CA (US)(21) Appl. No.: **10/596,998**(22) PCT Filed: **Jan. 10, 2005**(57) **ABSTRACT**

The present invention provides a novel class of azadecalin compounds and methods of using the compounds as glucocorticoid receptor modulators.